

Sterilization: Does It Work?

William A. Rutala, Ph.D., M.P.H., C.I.C

**Director, Statewide Program for Infection Control and Epidemiology
and Professor of Medicine, University of North Carolina at Chapel
Hill, NC, USA**

**Former Director, Hospital Epidemiology, Occupational Health and
Safety, UNC Health Care, Chapel Hill, NC (1979-2017)**

DISCLOSURES

2018-2019

- **Consultations**
 - ASP, PDI
- **Honoraria**
 - PDI, ASP, 3M
- **Scientific Advisory Board**
 - Kinnos
- **Grants**
 - CDC

Goal

**Prevent All Infectious Disease Transmission Associated
with Medical/Surgical Devices**

Evidence-Based Recommendation for Sterilization of Endoscopes

(FDA Panel Recommendation for Duodenoscopes, May 2015; more peer-reviewed publications (>150) for the need for shifting from disinfection to sterilization than any other recommendation of AAMI, CDC [HICPAC], SHEA, APIC, SGNA, ASGE)

>130 plus endoscope-related outbreaks

GI endoscope contamination rates of 20-40% after HLD

Scope commonly have disruptive/irregular surfaces

>50,000 patient exposures involving HLD

GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

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Gastrointestinal Endoscopes A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.¹ Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.¹

In this issue of *JAMA*, Epstein and colleagues² report findings from their investigation of a cluster of New Delhi metallo- β -lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.^{3,4} High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.³ However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.^{3,5} However, until now,



Related article page 1447

Disinfection and Sterilization

WA Rutala, DJ Weber, and HICPAC, www.cdc.gov

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (developed 1968).

CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL - objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).

Disinfection and Sterilization

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643.

EH Spaulding believed that how an object will be disinfected depended on the object's intended use (**proposed clarification**).

CRITICAL - objects which **directly or indirectly/secondarily** (i.e., via a **mucous membrane such as duodenoscope, cystoscope, bronchoscope**) enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (high-level disinfection [HLD]) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL - objects that touch only intact skin require low-level disinfection (or non-germicidal detergent).

Reason for Endoscope-Related Outbreaks

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Margin of safety with endoscope reprocessing minimal or non-existent
- **Microbial load**
 - ◆ GI endoscopes contain 10^{7-10}
 - ◆ Cleaning results in 2-6 \log_{10} reduction
 - ◆ High-level disinfection results in 4-6 \log_{10} reduction
 - ◆ Results in a total 6-12 \log_{10} reduction of microbes
 - ◆ Level of contamination after processing: 4 \log_{10} (maximum contamination, minimal cleaning/HLD)
- **Complexity of endoscope and endoscope reprocessing**
- **Built-up biofilms-could contribute to failure of endoscope reprocessing**

What Is the Public Health Benefit?

No ERCP-Related Infections

Margin of Safety-currently nonexistent; sterilization will provide a safety margin ($\sim 6 \log_{10}$). To prevent infections, all duodenoscopes should be devoid of microbial contamination.

HLD ($6 \log_{10}$ reduction)

vs

Sterilization ($12 \log_{10}$ reduction=SAL 10^{-6})

How Do We Reduce Infection Risk and Ensure Patient Safety?

- Improved cleaning
- Shift from HLD to sterilization

New Cleaning Chemistries/Methods

Antimicrobial (reduce microbial load by 4-6 \log_{10})

Biofilm inhibiting or destruction properties

Automate cleaning (standardize)

Cleaning verification-predictive of microbial contamination

How Do We Reduce Infection Risk and Ensure Patient Safety?

- Improved cleaning
- Shift from HLD to sterilization

Where are we in reducing infection risk?

Potential Future Methods to Prevent Endoscope-Related Outbreaks

Rutala, Weber. Am J Infect Control. 2016;44:e1-e6; Rutala, Weber ICHE. 2015;36:643; Rutala, Weber. AJIC. 2019;47:A62

How can we reduce infection risk?

- Optimize current low temperature sterilization methods (e.g., cycle changes, booster) or new LTST proving SAL 10^{-6} achieved (2 LTS technologies, FDA-cleared)
- Disposable sterile GI endoscopes/bronchoscopes (2 manufacturers)
- Steam sterilization for GI endoscopes (1 bronchoscope manufacturer)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, stool or blood tests to detect GI cancer, stool DNA test)

Potential Future Methods to Prevent Endoscope-Related Outbreaks

- Improved GI endoscope design (to reduce or eliminate reprocessing challenges-based on 50y of experience unlikely to resolve problem; closed channel duodenoscopes increased risk)
 - FDA recommends disposable end caps to reduce risk of infection associated with duodenoscopes. FDA cleared two duodenoscopes with disposable endcaps (Pentax and Fuji).
August 2019

Sterile, Disposable GI Scopes Must Have Acceptable Diagnostic and Therapeutic Capabilities

(FDA Clearance September 2016)



True Cost of Reprocessing Endoscope

Ofstead et al. Communique. Jan/Feb 2017

\$114.07-\$280.71

**Technology must be acceptable in
terms of sterilization performance,
scope performance (disposable), costs,
throughput and materials compatibility**

Sterilization: Does It Work?

Sterilization of “Critical Objects”

(legally marketed sterilizers)

Rutala, Weber. AJIC. 2019;47:A3-A9

Steam sterilization

Hydrogen peroxide gas plasma

Ethylene oxide

Ozone and hydrogen peroxide

Vaporized hydrogen peroxide

Liquid Chemical Sterilant Processing System

- Liquid chemical sterilant processing system (LCSPS)
 - All LCSPS have the same limitation in that final devices emerge wet and unwrapped from the processor (**not terminally sterilized**)
 - The LCSPS **rinse water is not described as sterile**
 - **Not considered comparable to other legally marketed sterilizers**
 - FDA consider steam sterilization, HP gas plasma, VHP, ETO, and HP-Ozone sterilizers (which the agency has cleared) to be fully validated terminal sterilizers which provide terminally sterilized products

Sterilization: Does It Work?

WA Rutala, DJ Weber, and HICPAC, www.cdc.gov

Factors affecting the efficacy of sterilization

- Bioburden
- Cleaning
- Pathogen type
- Protein and salt
- Biofilm accumulation
- Lumen length and diameter
- Restricted flow

Robustness

Ability to sterilize in presence of organic matter



Penicylinders Sterilized by Various Low-Temperature Sterilization Methods

Study conditions not representative of practice or manufacturer's recommendations

Alfa et al. Infect Cont Hosp Epidemiol 1996;17:92-100.

Challenge:	12/88	100%ETO	HCFC-ETO	HPGP
10% Serum, 0.65% Salt (7 organisms, N=63)	97%	60.3%	95.2%	37%
No Serum or Salt, (3 organisms, N=27)	100%	100%	96%	100%

The three organisms included: *E. faecalis*, *M. chelonei*, *B. subtilis* spores. The seven organisms included: *E. faecalis*, *P. aeruginosa*, *E.coli*, *M. chelonei*, *B. subtilis* spores, *B. stearothermophilus* spores, *B. circulans* spores

Comparative Evaluation of the Microbicidal Activities of Sterilization Technologies in the Presence of Salt and Serum

Study conditions not representative of practice or manufacturer's recommendations

Rutala et al. ICHE, In press

Steam sterilization is the most effective and has the largest margin of safety, followed by ETO and HPGP and lastly, VHP

Organism	Steam	ETO	HPGP	VHP
Vegetative Cells-Pa, Ec, VRE, Sa, Mt	0% (0/140)	3% (6/220)	3% (5/180)	72% (129/180)
Spores-Ba, Gs, Cd	0% (0/80)	0% (0/90)	0% (0/90)	86% (77/90)
Overall Total	0% (0/220)	2% (6/310)	2% (5/270)	76% (206/270)

Complex Instrumentation

Sterilant penetrates long, narrow lumens
and achieves SAL 10^{-6} (comply with
manufacturer's instructions for use-lumen
diameter, length, loading practices, weight)

**Sterile lumen
carrier 2 cm
long, 3 mm
internal diameter**



**Bacterial inoculum
(10^6 cfu) in 10% serum
and 0.65% salt**

**Dried overnight at
Room temperature**



**Latex Linkers
or
Porous Linkers**



**Assembled dimensions:
125 cm long x 3 mm internal diameter**

Lumens Sterilized by Various Low-Temperature Sterilization Methods

Study conditions not representative of practice or manufacturer's recommendations
Alfa et al. Infect Cont Hosp Epidemiol 1996;17:92-100.

Challenge:	12/88	100%ETO	HCFC-ETO	HPGP
10% Serum, 0.65% Salt (7 organisms, N=63)	44%	39.7%	49.2%	35%
No Serum or Salt, (3 organisms, N=27)	ND	96.3%	96.3%	ND

The three organisms included: *E. faecalis*, *M. chelonei*, *B. subtilis* spores. The seven organisms included: *E. faecalis*, *P. aeruginosa*, *E.coli*, *M. chelonei*, *B. subtilis* spores, *B. stearothermophilus* spores, *B. circulans* spores

Comparison of LCSPS to ETO for Long Narrow Lumens (\log_{10} CFU/lumen)

Alfa et al. ICHE 1998;26:469

Liquid chemical sterilant (LCS) resulted in 6 \log_{10} in microbial load compared to 2.5-5 \log_{10} reduction for 100% ETO

Sterilizer and linker type	<i>M. chelonae</i>	<i>E. faecalis</i>	<i>B. subtilis</i>
LCSPS			
Control	5.84	6.59	6.05
Porous	0	0	0
100% ETO			
Control	5.62	6.75	6.13
Porous	0	1.70	1.31
Latex	0	2.67	3.60

Sterilization: Does It Work?

Conclusions

- Steam sterilization is the most robust and has the largest margin of safety, followed by ETO and HPGP and lastly, VHP
- Liquid chemical sterilant processing system was the most effective for achieving a $6 \log_{10}$ reduction of microbes in narrow flexible lumens in the presence of salt and organic matter
- LTST (ETO, HPGP, VHP) demonstrate a significant number of failures in presence of serum or salt and long, narrow lumen devices
- Salt, protein, lumens provide protection for spores and bacteria
- All technologies have limitations
- Sterilization is SAL 10^{-6} (1 in 1M chance of non-sterile unit), $12 \log_{10}$ reduction; 2 LTST are FDA cleared for sterilization of GI scopes

Sterilization: Does It Work? Yes

www.disinfectionandsterilization.org

How Can We Prevent All Infectious Disease Transmission by Medical Devices?

Optimize LTST (ETO, HPGP, VHP, HP-Ozone, LCS?), develop new LTST, steam, sterile disposable, non-endoscopic methods, improve design

THANK YOU!
www.disinfectionandsterilization.org



Steris System 1E

- SS1E-liquid chemical sterilant processing system (LCSPS)
 - All LCSPS have the same limitation in that final devices emerge wet and unwrapped from the processor (not terminally sterilized)
 - The SS1E rinse water is not described as sterile
 - FDA consider steam sterilization, HP gas plasma, VHP, ETO, and HP-Ozone sterilizers (which the agency has cleared) to be fully validated terminal sterilizers which provide terminally sterilized products

UNC Health Care Policy-SS1E

- As a general rule, the Steris System 1E will not be used to reprocess critical items unless the item cannot be sterilized by other legally marketed sterilization methods (e.g., SS, ETO, HP gas plasma, VHP, ozone) validated for that type of device

How Will We Prevent Infections Associated with Medical Devices (HLD to Sterilization)?

- FDA Panel has accepted sterilization for duodenoscopes
- Sterilization manufacturer's are optimizing their LTST to sterilize GI endoscopes/bronchoscopes
- Sterile, single use GI endoscopes are developed
- Professional organizations (SHEA, APIC, AORN, SGNA, ASGE, IAHCSMM, AAMI) are starting to embrace conversion. Scheduled presentations on transition from HLD to sterilization with AAMI Sterilization/HLD Committees, APIC, SGNA, Canadian APIC, World Sterilization Congress
- Researchers/Opinion Leaders need to continue the science-based evaluations on why conversion is necessary

Duodenoscopes and Endoscope Reprocessing :

A Need to Shift from Disinfection to Sterilization

- Comply with endoscope reprocessing guidelines
- Implement enhanced method for reprocessing duodenoscopes. Doing nothing is not an option.
- Only when we implement new technologies (e.g., single-use sterile scopes; sterilization of GI scopes with technology that achieves an SAL 10^{-6}) will we eliminate the risk of infection